Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2003455	02/06/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Escribano	Carretera Pr 639 Km 2 Bo Sabana Hoyos, Sabana Hoyos, PR	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA Recertification survey at the Laboratorio Clnico Escribano on February 6, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on February 6, 2026.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (year 2025), CASPER Report 0155D, and interview with the laboratory director on February 6, 2026, at 9:40 a.m., the laboratory failed to take and document corrective action when it obtained an unsatisfactory score for the sodium analyte in the first proficiency testing event of 2025. The laboratory processed and reported 3,586 out of 3,586 sodium analytes from October 2024 through May 2025. The findings included: 1. The PRPTSP scores and CASPER Report 0155D were reviewed for the period of January 2025 through November 2025. 2. Review of PRPTSP scores and CASPER Report 0155D showed that the laboratory obtained an unsatisfactory score of 40% for sodium analyte in the first proficiency testing event of 2025; the laboratory did not take or document any remedial or corrective action. 3. On February 6, 2026, at 9:50 a.

	m., the laboratory director confirmed that the laboratory failed to take and document corrective action when the unsatisfactory sodium proficiency test scores were obtained. 4. The laboratory processed and reported 3,586 out of 3,586 sodium analytes from October 2024 through May 2025.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on the Quality Assessment (QA) records review (years 2024-2025) and interview with the laboratory director on February 6, 2026, at 10:00 a.m., the laboratory failed to establish and implement policies and procedures to monitor and evaluate patient complaint investigations as part of the general laboratory system. The findings include: 1. Review of the QA records showed that the laboratory did not have written policies and procedures to monitor and evaluate patient complaint investigations. 2. Review of the laboratory's QA records showed that patient complaint investigations were not evaluated for the years 2024 and 2025. 3. The laboratory director confirmed during interview on February 6, 2026, at 10:10 a.m., that the laboratory did not evaluate patient complaints investigations for the years 2024 and 2025.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of routine chemistry calibration verification records (years 2025-2026) and interview with the laboratory director on February 6, 2026, at 12:20 p.m., the laboratory failed to perform calibration verification at least every six months for routine chemistry testing performed on the RX Daytona Chemistry Analyzer, the laboratory processed and reported 12,440 out of 12,440 routine chemistry analytes

	from January 2025 through February 5, 2026. The findings included: 1. The laboratory used the RX Daytona Chemistry Analyzer to perform routine chemistry testing. 2. The laboratory did not perform calibration verification for routine chemistry testing at least every six months, as required, since July 2024. 3. On February 6, 2026, at 12:45 p.m., the laboratory director confirmed that the laboratory did not perform calibration verification during the year 2025 and January 2026. 4. The laboratory processed and reported 12,440 out of 12,440 routine chemistry analytes from January 1, 2025, through February 5, 2026, without completing the required calibration verification.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a review of the Quality Assessment (QA) program (years 2024-2025) and interview with the laboratory director on February 6, 2026, at 10:05 a.m., the laboratory failed to follow its established QA program to monitor and evaluate the laboratory's turn-around times (TAT) as part of the postanalytical system. The findings included: 1. On February 6, 2026, at 10:00 a.m., review of the laboratory's QA program showed that the laboratory required annual evaluation of TAT. 2. Review of QA records showed that the laboratory last evaluated TAT in 2023 and did not perform TAT evaluations for the years 2024 and 2025. 3. During interview on February 6, 2026, at 10:15 a.m., the laboratory director confirmed that the laboratory did not perform TAT evaluations during the years 2024 and 2025.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on a review of Puerto Rico Proficiency Testing (PRPTSP) scores (year 2025), the CASPER Report 0155D, and laboratory director interview on February 6, 2026, at 2:00 p.m., the laboratory director failed to take corrective action when it obtained an unsatisfactory score for the sodium analyte in the first proficiency testing event of 2025. Refer to D2094.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

	This STANDARD is not met as evidenced by: Based on Quality control (2025) record review, Quality assessment program (year 2024- 2025) and interview with the laboratory director on February 6, 2026, at 2:00 p. m., the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control and quality assessment requirements. Refer to D5205, D5439 and D5891.